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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,146	03/31/2005	Martin A Smith	58142(45858)	2874

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EXAMINER	
TUNG, JOYCE	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
05/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,146	SMITH ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17,18,20-35 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/20/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed 1/25/10 to the Office action has been entered. Claims 1-15, 17-18, 20-35 and 66 are pending.

2. The rejection of claims 1-15, 17-18, 20-35 and 66 under 35 U.S.C. 112, first paragraph is withdrawn because of the argument filed 1/25/10.

3. All of the previously presented art rejections are withdrawn. This office action contains new grounds for rejection, therefore it is made non-final.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-12, 14, 15, 17-18, 20-21, 23-35 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US Patent No. 6,645,717, issued Nov. 11, 2003; previously

cited) as evidenced by Burgoyne (U.S. Patent No. 5,496,562 A; cited in the IDS) and Mitchell (WO 00/21973; previously cited).

Regarding claims 1, 35 and 66, Smith et al. teach a method for isolating and storing nucleic acid, comprising:

a. providing a solid phase medium (Smith et al. disclose a medium including a support for immobilizing a genetic material (see column 4, lines 12-13; col. 6, lines 32-40);

d. contacting the solid phase medium with a solution comprising (i) an anionic surfactant or detergent, (ii) a weak base, and (iii) a chelating agent by adding the solution comprising (i) the anionic surfactant or detergent, (ii) the weak base, and (iii) the chelating agent to the solid phase medium (col. 6, lines 54-67; col. 7, lines 1-8);

b. applying a sample comprising cells containing nucleic acid to the solid phase medium (Smith et al. disclose a method which includes the steps of immobilizing the genetic material on a support and while enabling cellular lysis and releasing the genetic material from the lysed cells (see column 4, lines 19-22; col. 6, lines 1-6).

c. retaining the cells with the solid phase medium as a cellular retentate (Smith et al. disclose a method which includes the steps of immobilizing the genetic material on the support (see column 4, lines 19-22));

e. lysing the intact cells in the cellular retentate to form a cell lysate while retaining the cell lysate in the medium, the cell lysate comprising the nucleic acid (col. 5, lines 52-67; col. 6, lines 1-6);

f. subsequently drying the solid phase medium with the cell lysate comprising the nucleic acid (col. 11, lines 1-6); and

g. storing the dried solid phase medium with the nucleic acid (col. 9, lines 4-11).

Smith et al. do not teach that the solution of step (d) is applied to the support subsequently to immobilization of cells onto the support. However, as evidenced by Mitchell et al., the order of steps can be reversed, leading to the same end result, i.e. nucleic acid from lysed cells immobilized onto a filter (see Mitchell et al. page 2, third paragraph), which cites the method comprising:

"According to the present invention, there is provided a method for isolating nucleic acid which comprises:

(a) applying a sample comprising cells containing nucleic acid to a filter, whereby the cells are retained as a retentate and contaminants are removed;

(b) lysing the retentate from step (a) whilst the retentate is retained by the filter to form a cell lysate containing the nucleic acid;

(c) filtering the cell lysate with the filter to retain the nucleic acid and remove remaining cell lysate;

(d) optionally washing the nucleic acid retained by the filter; and

(e) eluting the nucleic acid, wherein the filter composition and dimensions are selected so that the filter is capable of retaining the cells and the nucleic acid."

As stated in MPEP 2144.04 IVC:

C. Changes in Sequence of Adding Ingredients

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter

impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

Also, MPEP 2111.01 II (underlined):

"Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). See also *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004)(discussing recent cases wherein the court expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment);< *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) ("Interpretation of descriptive statements in a patent's written description is a difficult task, as an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims 'in view of the specification' without unnecessarily importing limitations from the specification into the claims."); *Altiris Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371, 65 USPQ2d 1865, 1869-70 (Fed. Cir. 2003) (Although the specification discussed only a single embodiment, the court held that it was improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on the performance of the method steps, and the specification did not directly or implicitly require a particular order).

Therefore it would have been prima facie obvious to one of ordinary skill in the art to reverse the order of steps in the method of Smith et al., since the end result is still the same.

Regarding claim 2, Smith et al. teach washing the nucleic acid (col. 8, lines 59-63; col. 10, lines 46-48).

Regarding claims 3, 6-8 and 66, Smith et al. disclose that the blood is spotted to the filter membrane of the invention, air dried for two minutes and stored at room temperature for 19 weeks (see column 17, lines 66-67 and column 18, lines 1-6).

Regarding claims 4, 35 and 66, Smith et al. disclose that the genetic material is eluted from the medium (see column 4, lines 23-25; col. 6, lines 4-11; col. 7, lines 24-31).

Regarding claim 5, Smith et al. teach washing the filter membrane before elution (col. 10, lines 46-48).

Regarding claim 9, Smith et al. teach storage of the medium for years (col. 9, lines 4-11).

Regarding claims 10 and 11, Smith et al. disclose that the medium is a plurality of fibers with disordered structure (see column 5, lines 45-46 and fig. 9).

Regarding claim 12, Smith et al. teach a variety of filter materials (col. 6, lines 32-40), but do not specifically teach fiber diameters in the range from 1 to 10 microns and pore sizes from 0.2 to 2.7 microns. As evidenced by Mitchell et al., filters appropriate for immobilization of DNA included filters with fiber diameters from 1 to 15 microns (page 9, third paragraph).

Regarding claims 14-15 and 66, Smith et al. disclose that the filter media is glass, silica, plastics or cellulose-based (see column 6, lines 32-40; Fig. 9).

Regarding claims 17 and 20, Smith et al. disclose that the chemical coating solution includes a week base, chelating agent, an anionic surfactant or detergent which can be sodium dodecyl sulfate and urate salt (see column 6, lines 62-67 and column 7, lines 1-2).

Regarding claim 18, Smith et al. teach that the coating solution can have a composition as described in U.S. Patent No. 5,496,562 (Burgoyne), for example, (col. 6, lines 54-59). As evidenced by Burgoyne, the SDS concentration can be 2% (col. 4, lines 35-40).

Regarding claim 21, since the cells contain nuclei, which contain DNA, the cellular retentate inherently contains material from cell nucleus.

Regarding claims 23-24, in the disclosure, Smith et al. teach different fibers for the filters (column 6, lines 32-40). As evidenced by Mitchell et al., binding of the nucleic acid to filters is generally non-ionic (page 9, third paragraph). Since the known non-ionic interactions include the ones listed in claim 24, and due to the complexity of the system, at least one type of the interaction listed in claim 24 inherently occurs within DNA immobilized onto a membrane. For example, as stated by Mitchell et al. (page 9, first paragraph):

"It is postulated that nucleic acid-nucleic acid interactions themselves are important in maintaining a sufficiently high cross-sectional area to retard movement of the nucleic acid through the filter".

Since DNA-DNA interactions include at least hydrogen bonding and dispersion forces, the claim's limitations are anticipated.

Regarding claim 25, Smith et al. disclose that the method includes the steps of immobilizing the genetic material on the support and while enabling cellular lysis and releasing the genetic material from the lysed cells (see column 4, lines 10-17). Therefore, the nucleic acid is inherently physically restrained on the filter.

Regarding claim 26, Smith et al. do not explicitly disclose that a chaotrope is used in his invention. However, in the method of Smith et al. as disclosed, there is no a chaotrope used and suggested.

Regarding claim 27, Smith et al. depositing whole blood onto a filter (col. 10, lines 42-45), therefore they inherently teach concentrating the cells in the solid phase medium.

Regarding claims 28, 29 and 66, Smith et al. disclose that the support is heated between 65^0C and 100^0C for elution (see column 8, lines 51-58).

Regarding claims 30-32, Smith et al. teach application of whole blood to the filter and retaining specifically white blood cells (col. 10, lines 42-44).

Regarding claims 33 and 34, Smith et al. teach genomic DNA (col. 10, lines 44-48).

Smith et al. do not specifically teach removing contaminants from immobilized cells before cell lysis. However, washing cells before lysis to obtain genetic material is well established in the art at the time of the invention. Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have added a cell-washing step in the method of Smith et al., since such wash would improve quality of nucleic acid obtained from the cells.

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. Patent No. 6,645,717, issued Nov. 11, 2003; previously cited), as evidenced by Burgoyne (U.S. Patent No. 5,496,562 A; cited in the IDS) and Mitchell (WO 00/21973; previously cited), as applied to claims 1 and 10 above and evidenced by Whatman filter paper overview (downloaded from the internet on May 21, 2010)

The teachings of Smith et al. are set forth in section 4 above. Smith et al. do not disclose the pore size from 0.2 um to 2.7 um.

As evidenced by the range of filter materials and filters provided by Whatman, the filters have a variety of pore sizes between 0.015 to 12 microns. Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have picked a filter with pore size appropriate to the type of cells being lysed, for example.

8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. Patent No. 6,645,717, issued Nov. 11, 2003; previously cited), as evidenced by Burgoyne (U.S.

Patent No. 5,496,562 A; cited in the IDS) and Mitchell (WO 00/21973; previously cited), as applied to claim 1 above, and further in view of Qiagen Genomic DNA Handbook (pages 17-22, August 2001)

A) The teachings of Smith et al. are set forth in section 4 above. Smith et al. do not disclose the limitations of claim 22.

Regarding claim 22, Qiagen protocol for genomic DNA purification from whole blood teaches sequential lysis of first blood cell membranes, washing away the debris from the nucleic and then lysing the cleaned nuclei to obtain genomic DNA (pages 21-22).

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used a two-step cell lysis protocol of Qiagen in the method of obtaining genomic DNA from whole blood of Smith et al. The motivation to do so would have been that such protocol allowed purification of nuclei away from cell contaminants, which might interfere with subsequent reactions in which the DNA was used, such as PCR.

Summary

9. No claims are allowed.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joyce Tung/
Examiner, Art Unit 1637
May 15, 2010

/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637
May 21, 2010